Screening for Giardia/Cryptosporidium infections using an enzyme immunoassay in a centralized regional microbiology laboratory


Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
Two screening tests for Giardia and Cryptosporidium (G/C) infections were examined. One was the stool ova and parasite method (O&P), based on microscopic examination using a modified iron haematoxylin-kinyoun stain and ethyl acetate concentration procedures. The other was enzyme immunoassay (EIA). The two testing methods were described in detail.

Type of intervention
Screening.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised stool specimens submitted for parasitologic examination.

Setting
The setting was a laboratory. The economic study was carried out in Canada.

Dates to which data relate
The effectiveness and resource use data were gathered from May 1999 to April 2002. The price year was unclear.

Source of effectiveness data
The effectiveness evidence was derived from a single study.

Link between effectiveness and cost data
The costing was carried out prospectively on the same sample of specimens as that included in the effectiveness study.

Study sample
All stool specimens admitted for parasitologic examination during the 3-year study period were included in the study. Overall, 39,293 individual stool specimens were considered. Other details of the study sample were not reported.

Study design
This was a diagnostic study that was carried out at the Calgary Laboratory Services Microbiology Laboratory in Calgary. Changes were made to the regional microbiology requisition in 1999 so that physicians could order either a
G/C EIA screen or a stool O&P examination. Physicians completed the clinical history portion of the requisition in order for a stool O&P examination to be carried out. A G/C EIA screen was initially conducted when ordered, and all positive tests were subsequently confirmed as being due to G/C by a direct fluorescent antibody (DFA) assay. Stool O&P testing was carried out only on samples for which the physician had ordered the test and provided a clinical history that met indications for testing. Unless a clinical history was provided on the requisition, only a G/C EIA screen was carried out. All stool specimens that had a stool O&P procedure were initially screened by the G/C EIA procedure. No follow-up was performed.

Analysis of effectiveness
All specimens initially included in the study sample were considered in the analysis of effectiveness. The outcome measures used were a number of epidemiologic and laboratory quality assurance end points:

- the rate of positivity of both tests for G/C infections each month, including the detection of outbreaks;
- test turnaround times for G/C EIA and stool O&P tests each month;
- the total number of stool parasitologic tests each month; and
- changes in physician ordering practices for stool parasitologic tests.

Effectiveness results
In total, 1,993 (5%) of all stool samples were positive for parasitic infection, and either Giardia or Cryptosporidium infections accounted for approximately half of all of the positive reports. In particular, 1,026 (51.5%) stool parasitologic tests from 830 patients were positive for either Giardia lamblia (G. lamblia) or Cryptosporidium, for an overall positivity rate of 2.6%. The overall rate of detection of G. lamblia infection (655/830, 79%) was almost four times that of Cryptosporidium parvum (C. parvum) (175/830, 21%). This represented a population prevalence of 19.6 per 100,000 population G. lamblia and 6.0 per 100,000 population for C. parvum.

Eighty-three patients with either Giardia or Cryptosporidium also had co-infection with the other enteric parasite, or with one or more other enteric parasites. The G/C EIA screen allowed cases from several waterborne Cryptosporidium outbreaks to be rapidly detected during the study.

There was a shift in the stool test ordering practices: 73% (range: 66 - 78) of the total number of test requests each month shifted to orders for a G/C EIA screen only. Implementation of the G/C EIA screen also resulted in a consistent decrease in the total number of orders for stool tests for enteric parasites; the decreased volume resulted from fewer requests to perform duplicate testing on a second or third stool sample.

All cases of giardiosis were initially found by the G/C EIA screen because of the far higher volume of stool samples being tested only by this method. Of the G/C EIA screen-positive cases, 330 (50.4%) of 655 were also confirmed by microscopic examination. Based on the clinical history, another 221 of these samples also had a stool O&P procedure performed that confirmed the positive G/C EIA screen result.

Although stool microscopy detected a proportionally higher rate of giardiosis cases (330/10,636, 3.1%) than the G/C EIA screen (655/39,293, 1.7%), the diagnosis would have been missed in two patients whose cases were identified only by the G/C EIA screen. Of the G/C EIA screen-positive cases, 105 (60%) of 175 were also confirmed by microscopic examination.

Although stool microscopy detected a proportionally higher rate of Cryptosporidium cases (105/10,636, 1.0%) than the G/C EIA screen (175/39,293, 0.5%), more cases overall were found by performing a G/C EIA screen on all stool specimens.

The results of the G/C EIA screen have been consistently reported since implementation, with more than 90% of the tests being completed within 24 hours of receipt of the specimen. The overall turnaround time of stool microscopy examination has improved due to the smaller volume of stool O&P tests requested.
Clinical conclusions
The effectiveness analysis showed that the change from O&P examination to EIA testing for the screening of G/C infection led to shorter turnaround times, higher detection rates (especially of cryptosporidiosis) and decreased volumes of stool samples submitted for parasitologic tests.

Measure of benefits used in the economic analysis
The health outcomes were left disaggregated and no summary benefit measure was used in the economic evaluation. In effect, a cost-consequences analysis was carried out.

Direct costs
The perspective adopted in the study was not explicitly stated, but it appears to have been that of the Calgary Health Region. The analysis of the costs considered labour and material costs. The unit costs were not presented separately from the quantities of resources used. The estimation of resource use was based on the volume of specimens analysed during the study period. The costs were estimated from the Calgary Health Region. It was assumed that almost 4% of all procedures were subsequently confirmed by a DFA procedure. Thirty per cent of the samples also had an O&P stained slide concentrate, and another 14% had a stained slide read to look for Dientamoeba fragilis. Discounting was not relevant since the costs were incurred during a short timeframe. A clear price year might have been helpful as the costs were estimated in different periods. It was unclear whether the costs referred to the fiscal year 2004.

Statistical analysis of costs
The costs were treated deterministically.

Indirect Costs
The indirect costs were not considered.

Currency
Canadian dollars (Can$).

Sensitivity analysis
Sensitivity analyses were not performed.

Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
The total costs were Can$192,429.60 for the stool O&P in the period 1998 - 1999 (i.e. prior to the implementation of the EIA test) and Can$200,298.00 with the combined G/C EIA plus stool O&P in the period 1999 - 2000. Thus, despite a dramatic reduction in the volume of tests ordered, the immediate effect of the change to the combined service was an increase of 4.1% in total costs, mainly due to the higher costs of reagents.

Based on the projected annual volume increase for stool parasitologic tests prior to implementation of the G/C EIA procedure, approximately 21,000 individual stool O&P tests would have been ordered in 2004. The total cost of providing a stool O&P service without G/C EIA screening in 2004 would have been Can$309,540. This was Can$53,925 (21.1%) more than the current total cost of providing this service through a combined stool O&P plus G/C EIA approach, which was Can$255,615.
It was also noted that the decrease in test volumes, combined with the fact that it took much less time to perform a G/C EIA assay than a stool O&P test, resulted in an immediate labour saving of 1.5 full-time equivalents (FTE) (1.0 FTE medical laboratory technologist and 0.5 FTE medical laboratory assistant).

**Synthesis of costs and benefits**
A synthesis of the costs and benefits was not relevant because a cost-consequences analysis was performed.

**Authors’ conclusions**
The routine screening of stools for Giardia and Cryptosporidium (G/C) infections by enzyme immunoassay (EIA) in the Calgary region was clinically relevant and improved the timeliness and efficiency of the detection of G/C infections. The authors noted also that physicians’ compliance with the service change was immediate.

**CRD COMMENTARY - Selection of comparators**
The rationale for the choice of the comparators was clear and was justified by the authors. You should decide whether they are valid comparators in your own setting.

**Validity of estimate of measure of effectiveness**
The effectiveness evidence came from a diagnostic study, which was appropriate for the study question. A large sample of specimens was considered in the analysis, although power calculations were not performed. The assessment of the outcomes was not blinded, thus the presence of assessment bias cannot be ruled out. The accuracy of the EIA test was assessed using the DFA assay, which appears to have been considered as the 'gold' standard. No follow-up was carried out. The sequence of testing was not reported, and this might have affected the results of the analysis. The data came from multiple centres and were worked out at a single laboratory, thus the study sample was likely to be representative of the patient population.

**Validity of estimate of measure of benefit**
No summary benefit measure was used in the analysis because a cost-consequences analysis was conducted. Please refer to the comments in the 'Validity of estimate of measure of effectiveness' field (above).

**Validity of estimate of costs**
The analysis of the costs appears to have been restricted to the perspective of the regional laboratory. Thus, only those costs strictly related to the screening test were included in the analysis. Data on the unit costs and quantities of resources used were not presented separately, which limits the possibility of replicating the analysis in other settings. The cost estimates were treated deterministically and were specific to the study setting. Also, no sensitivity analyses on the costs or resource use were performed. The source of data reflected payment rates for the study laboratory. The price year was unclear.

**Other issues**
The authors did not make extensive comparisons of their findings with those from other studies, stating instead that the improvement in the rate of detection confirmed the experience of other investigators. The issue of the generalisability of the study results to other settings was not addressed. Sensitivity analyses were not performed, which limits the external validity of the study. The analysis referred to patients undergoing stool specimen tests for the screening of G/C infection, and this was reflected in the authors’ conclusions.

**Implications of the study**
The study results support the use of a rapid G/C EIA assay for stool screening.
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None stated.

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Other publications of related interest


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